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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,873	04/13/2004	Daniel R. Henderson	CELL-004CON2	3173

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EXAMINER	
WHITEMAN, BRIAN A	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 11/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/822,873	HENDERSON ET AL.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 55-92 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 55-92 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. 10/17/05.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 55-92 are pending.

The cancellation of claims 1-54 and addition of claims 55-60 in paper filed on 4/13/04 is acknowledged and considered by the examiner.

The addition of claims 55-92 in paper filed on 10/6/04 is acknowledged and considered by the examiner.

See interview summary (10/17/05) for clarification on claims with the same number.

In response to the instant office action, claims 55-92 should be renumbered starting at claim 61 and claims 55-60 should be cancelled.

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 55-92 have been renumbered 61-98.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 55-57, 59-60, and 66-72, drawn to a method for selective cytolysis of a target cell comprising contacting said target cell with an adenovirus vector comprising a cell type specific transcriptional regulatory element (TRE) operably linked to a first adenovirus gene essential for replication selected from the group

consisting of E1A, E1B, E4, wherein said adenovirus further comprises a cytotoxic gene, classifiable in class 424, subclass 93.2.

II. Claims 55-57, 61-62, and 66-72, drawn to a method for selective cytolysis of a target cell comprising contacting said target cell with an adenovirus vector comprising a cell type specific transcriptional regulatory element (TRE) operably linked to a first adenovirus gene essential for replication selected from the group consisting of E1A, E1B, E4, wherein said adenovirus further comprises a cytokine gene, classifiable in class 424, subclass 93.2.

III. Claims 55-57 and 63-72, drawn to a method for selective cytolysis of a target cell comprising contacting said target cell with an adenovirus vector comprising a cell type specific transcriptional regulatory element (TRE) operably linked to a first adenovirus gene essential for replication selected from the group consisting of E1A, E1B, E4, wherein said adenovirus further comprises the coding sequence for adenovirus death protein (ADP), classifiable in class 424, subclass 93.2.

IV. Claims 73-77, and 79-80 and 86-92, drawn to a method for selective cytolysis of a target cell comprising contacting said target cell with an adenovirus vector comprising a cell type specific transcriptional regulatory element (TRE) operably linked to a first adenovirus gene essential for replication selected from the group consisting of E1A, E1B, E4, wherein said adenovirus further comprises a cytotoxic gene and further comprising a second TRE, classifiable in class 424, subclass 93.2.

V. Claims 73-77, 81-82, and 86-92, drawn to a method for selective cytolysis of a target cell comprising contacting said target cell with an adenovirus vector comprising a cell type specific transcriptional regulatory element (TRE) operably linked to a first adenovirus gene essential for replication selected from the group consisting of E1A, E1B, E4, wherein said adenovirus further comprises a cytokine gene and further comprising a second TRE, classifiable in class 424, subclass 93.2.

VI. Claims 73-77 and 83-92, drawn to a method for selective cytolysis of a target cell comprising contacting said target cell with an adenovirus vector comprising a cell type specific transcriptional regulatory element (TRE) operably linked to a first adenovirus gene essential for replication selected from the group consisting of E1A, E1B, E4, wherein said adenovirus further comprises a coding sequence for ADP and further comprising a second TRE, classifiable in class 424, subclass 93.2.

The inventions are distinct, each from the other because of the following reasons:

Inventions IV and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination can use an adenovirus gene essential for replication selected from E1A, E1B and E4 and any cell type-specific transcriptional response element, including the

TREs recited in instant claim 57. Also, the prostate specific TRE doesn't have to be one of the prostate specific TREs recited in claim 68. In addition, the cytotoxic gene doesn't have to be the gene recited in claim 60. The subcombination has separate utility such as use in an in vivo method of gene therapy or in vitro method of killing tumor cells.

Inventions V and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination can use an adenovirus gene essential for replication selected from E1A, E1B and E4 and any cell type-specific transcriptional response element, including the TREs recited in instant claim 57. Also, the prostate specific TRE doesn't have to be one of the prostate specific TREs recited in claim 68. In addition, the cytokine gene doesn't have to be the gene recited in claims 62. The subcombination has separate utility such as use in an in vivo method of gene therapy or in vitro method of killing tumor cells.

Inventions VI and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination can use an adenovirus gene essential for replication selected from E1A, E1B and E4 and any cell type-specific transcriptional response element, including the

TREs recited in instant claim 57. Also, the prostate specific TRE doesn't have to be one of the prostate specific TREs recited in claim 68. In addition, the coding sequence of ADP doesn't have to be the amino acid sequences recited in claims 64. The subcombination has separate utility such as use in an in vivo method of gene therapy or in vitro method of killing tumor cells.

Inventions I, II, and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. In the instant case the different inventions are directed to distinct transgenes. The adenovirus of group I does not require the transgene of groups II and III and vice versa. Each invention performs this function using a structurally and functionally divergent material (transgene). Furthermore, searching the inventions of groups I, II and III together would impose a serious search burden. In the instant case, the search for cytotoxic gene, cytokine gene and coding sequence for adenovirus death protein is not coextensive. A search for an adenovirus comprising a cytotoxic gene would not overlap with a search for an adenovirus comprising cytokine gene or a coding sequence for adenovirus death protein. As such, it would be burdensome to search the inventions of groups I, II and III together. Therefore, each method is divergent in material and steps. For these reasons the Invention I, II and III are patentably distinct.

Inventions I, V, and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. In the instant case the

different inventions are directed to distinct transgenes. The adenovirus of group I does not require the adenovirus or transgene of groups V and VI and vice versa. Each invention performs this function using a structurally and functionally divergent material (transgene). Furthermore, searching the inventions of groups I, V and VI together would impose a serious search burden. In the instant case, the search for cytotoxic gene, cytokine gene and coding sequence for adenovirus death protein is not coextensive. A search for an adenovirus comprising a cytotoxic gene would not overlap with a search for an adenovirus comprising cytokine gene or a coding sequence for adenovirus death protein. As such, it would be burdensome to search the inventions of groups I, V and VI together. Therefore, each method is divergent in material and steps. For these reasons the Invention I, V and VI are patentably distinct.

Inventions II, IV, and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. In the instant case the different inventions are directed to distinct transgenes. The adenovirus of group II does not require the transgene of groups IV and VI and vice versa. Each invention performs this function using a structurally and functionally divergent material (transgene). Furthermore, searching the inventions of groups II, IV, and VI together would impose a serious search burden. In the instant case, the search for cytokine gene, cytotoxic gene and coding sequence for adenovirus death protein is not coextensive. A search for an adenovirus comprising a cytokine gene would not overlap with a search for an adenovirus comprising cytotoxic gene or a coding sequence for adenovirus death protein. As such, it would be burdensome to search the inventions of groups II,

IV, and VI together. Therefore, each method is divergent in material and steps. For these reasons the Inventions II, IV, and VI are patentably distinct.

Inventions III, IV, and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. In the instant case the different inventions are directed to distinct transgenes. The adenovirus of group III does not require the transgene of groups IV and V and vice versa. Each invention performs this function using a structurally and functionally divergent material (transgene). Furthermore, searching the inventions of groups III, IV, and V together would impose a serious search burden. In the instant case, the search for coding sequence for ADP, cytokine gene and cytotoxic gene is not coextensive. A search for an adenovirus comprising a coding sequence for ADP would not overlap with a search for an adenovirus comprising cytokine gene or a cytotoxic gene. As such, it would be burdensome to search the inventions of groups III, IV and V together. Therefore, each method is divergent in material and steps. For these reasons the Inventions III, IV and V are patentably distinct.

Claim 58 link(s) inventions I-II. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 58. Claim 78 link(s) inventions IV-V. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 78. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will

be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Because these inventions are distinct for the reasons given above and the search required for each Group listed above is not required for any other Group listed above and the search for each group is not co-extensive, restriction for examination purposes as indicated is proper.

It would be unduly burdensome for the examiner to search and consider patentability of all of the presently pending claims because it would require an undue burden for the examiner to search for each gene (ADP, cytokine, cytotoxic) listed in separate groups or using two TREs instead of one TRE. Thus, a restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 § 1.17(h).

If applicants elect Group I-III, applicants are further required to elect a species from the following:

This application contains claims directed to the following patentably distinct species of the claimed invention: first cell type-specific transcriptional response element selected from the group recited in claim 57.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 55 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

If applicants elect Group IV-VI, applicants are further required to elect a species from the following:

This application contains claims directed to the following patentably distinct species of the claimed invention: first cell type-specific transcriptional response element selected from the group recited in claim 77.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 73 is generic.

A telephone call was made to Linda Judge on 10/17/05 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, acting SPE - Art Unit 1635, can be reached at (571) 272-0811.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman
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